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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/335,689	06/18/99	TOUSIGNANT	J 6969.0028

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EXAMINER
SCHNIZER, R

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 04/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

09/335,689

Applicant(s)

Tousignant et al

Examiner

Richard Schnizer

Art Unit

1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Apr 4, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attached.

4. ☐ Applicant's reply has overcome the following rejection(s):

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: None

Claim(s) objected to: _____

Claim(s) rejected: 1-30

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

11. ☐ Other:

Art Unit:

ADVISORY ACTION

Applicant's proposed amendments raise new issues that would require further consideration.

The proposed amendments would require micellar complexes wherein the variation in size distribution of the micellar complexes is less than or equal to 20% with respect to the mean size of the micellar complexes. It is unclear whether this limitation allows a total variation of 20%, *e.g.* 10% above the mean and 10% below the mean, or whether it allows a distribution of 20% above the mean and 20% below the mean.

Applicant's proposed amendments and response fail to place the application in condition for allowance.

As stated in Paper No. 8, the specification fails to enable the claimed methods of making populations of micellar complexes with the recited variation in size. See Figs. 2-4 of the specification. In no case does the specification disclose the production of a group of micellar complexes which vary in size by less than 20% from the average size of the group. For example, in Fig. 3C complexes are produced which range in size from 0-100 nm, thus the size distribution of the complexes is from 0-100 nm. The apparent average size of these micelles is about 30-40 nm. Thus the variation in size distribution (100 nm) exceeds 100% of the mean size of the micelles (30-40 nm).

Art Unit:

Applicant argued previously in Paper No. 9 that "the Examiner appears to be looking at the range, in size, of micellar complexes made by the present invention, rather than the size distribution." In response, the Examiner asserts that he is looking at the proposed amendment which recites "the variation in size distribution". As noted above, the micelles in Example 3C are distributed amongst a range of sizes approaching 0 nm and extending to about 100 nm. While the majority of micelles are distributed in the range of 30-40 nm, leading the examiner to estimate an average size of 30-40 nm, the distribution of sizes varies from about 0 to about 100 nm. For this reason, the variation in size distribution exceeds 100% of the mean size of the micelles.

Conclusion

The rejections of claims 1-3, 6-14, 16-19, 21-30 under 35 USC 102, and of claims 1, 4, 15 and 20 under 35 USC 103 would have been overcome by Applicant's amendment, if the amendment had been entered.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 103-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is usually in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014.

Art Unit:

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Patsy Zimmerman whose telephone number is 703-308-8338.

Richard Schnizer, Ph.D.

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